K111668

EMERGO GROUP

AUG 19 2011

Section 005 – Traditional 510(k) Summary

As required in 21CFR 807.92, we hereby submit this 510(k) Summary:

510(k) owners name, address, phone, fax, contact person & prep date

The 510(k) owner is NeoDental Chemical Products Co., Ltd.

3-1-3 Hiroo, Shibuyaku, Tokyo, Japan 150.

Phone - 3 (3400) 3768,

Fax - 3 (3499) 0613.

The contact person is Mr. Nobuki Ishikawa, Treasurer, NeoDental International, Inc.

510(k) preparation date – 05 May 2011

Name of the device, trade name, proprietary name, and classification name

Trade name: Cavios Cavity Liner

Common name: Cavity Liner

Classification name: Calcium hydroxide cavity liner (21 CFR 872.3250, Product Code EJK).

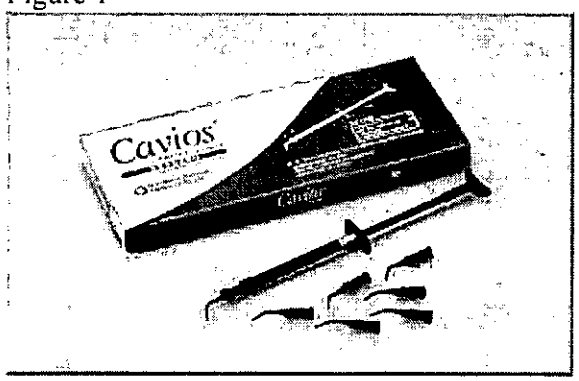
Predicate Device:

The legally marketed predicate for the Cavios® Cavity Liner is UltraBlend Plus Calcium Hydroxide Dentin Liner and Protective Base (K970113).

Device Description:
NeoDental Chemical Products, Inc, (NeoDental) wishes to submit their **Cavios® Cavity Liner Device Material** for 510(k) clearance.

Cavios®, (shown in **Figure 1**) is a light cured single-component yellow-white paste for use as a dentin liner and base. The product is preloaded into syringes and expressed via the syringe plunger through single-use disposable tips. Following the application, Cavios® is cured (polymerized) with a light source (approximately 470 nm). Following polymerization, the restorative materials, amalgam, etc., may be placed.

Figure 1



Cavios® is packaged as a multiple use syringe, with new tips being attached for each patient. The syringe can be used until empty. The syringe is kept capped between uses and is fitted with a new tip just prior to use. The syringe is cleaned with an alcohol wipe before and after use.

Indication for Use:

Cavios® Cavity Liner is to be applied to the interior of a prepared cavity prior to the insertion of restorative materials. Cavios® Cavity Liner is indicated for use in the general dental population.

Intended Use:

Cavios® Cavity Liner is a yellow-white, single-component, light cured, material for dentin liner and base. Cavios® is easily expressed through the plunger type syringe with single use disposable tips. Cavios is intended for the general dental patient population and can be delivered directly into the prepared cavity. The syringe applicator permits application directly into the cavity. The Cavios® material provides excellent radiopacity.

The Intended Use information from the predicate product is equivalent and is reproduced below:

Ultradent Products, Inc's "UltraBlend Plus" calcium hydroxide dentin liner and protective base" is indicated as a cavity liner and/or base material before placing either composite or amalgam. It is also used for pulp capping and small direct exposures without hyperemic bleeding. UltraBlend Plus may also be used as an opaque when amalgam has "tattooed" dentin and an esthetic restoration is being placed or when performing a crown repair where the metal is showing.

As is documented in the comparison of Indications For Use, the Cavios® and Ultra-Blend Plus dentin liner and base are indicated for the same use, share the same clinical indication, clinical setting, target population, anatomical sites, intended use, prescription requirement, storage conditions and method of application.

Technological characteristics – Cavios versus the predicate device

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A technical comparison of the subject device to the predicate device is detailed in the *Substantial Equivalence* discussion below. Cavios was designed, tested and compared to Ultra-Blend plus (see the comparison table below).

Both Cavios® and Ultra-Blend utilize a single-component material that is photo-polymerized to form a liner for subsequent placing of dental restorations. The primary difference between the subject device and the predicate is a minor difference in the filler material. Both products utilize urethane dimethacrylate as the photo-polymerizing base. Cavios employs α-Tricalcium phosphate whereby Ultra-Blend plus uses calcium hydroxyapetite as fillers. Both materials are mixed to maintain the properties of the paste and filling material. Both products utilize barium sulfate to provide radio opacity.

The Cavios® Cavity Liner has been evaluated according to the recognized consensus standards and other testing (see sections 15 and 18) and was found to conform to all requirements. Test data is further discussed in the respective sections (biocompatibility and bench testing)

Non clinical test data:

A number of testing standards were utilized to evaluate Cavios (see Sections 15 and 18). Per ISO 10993-1, Annex A, Cavios can be categorized as follows:

<table>
<tr><th colspan="2">Medical device categorization by:</th><th colspan="2">Biological effect for consideration</th></tr>
<tr><td rowspan="2">Nature of body contact</td><td>Category</td><td>External Communicating Device</td><td rowspan="2">Cytotoxicity
Sensitization
Irritation
System Toxicity
Subchronic Toxicity
Genotoxicity
Implantation</td></tr>
<tr><td>Contact</td><td>Tissue/bone/dentin</td></tr>
<tr><td colspan="2">Contact duration</td><td>C – Permanent (> 30 days)</td><td></td></tr>
</table>

Urethane resin (UDMA), the main ingredient of Cavios has been widely used in dental restorative materials as a "composite resin". Alpha tricalcium phosphate and barium

sulfate, ingredients of Cavios, have been widely used in filling materials as filler or radiopaque materials and are free of harmful substances.

ISO 10993-1 presents a schema for deciding whether biocompatibility evaluation is required.

Is there either direct or indirect contact? YES

Is the material the same as in a commercially available device? YES

Does the device have the same chemical composition as these devices? YES

Are the manufacturing and sterilization processes the same? YES

Is the contact to the body the same? YES

Given this schema, there is no need to select biological tests. Nonetheless, we have obtained selected ISO 10993 test results for the Cavios product as follows.

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Table of biocompatibility tests conducted

Biological Test	Date & Lab	Method	Result
Genotoxicity ISO 10993-3	9/16/2002 Covance	Bacterial strains (TA98, TA100, TA1535, WP2uvrA), S9+ S9 methods	Negative
Hemolysis	10/7/2002 Covance	Hemolysis in rabbit whole blood assay	Cavios was tested for Hemolysis both directly and as extracts. Test article induced 0.1% to 2.8% hemolysis. Cavios is considered negative in this assay.
Cytotoxicity ISO 7405 6.2/6.3, ISO 10993-5	9/18/2002 Covance	Agar Overlay	Not cytotoxic to cultured L929 mouse fibroblast cells after a 24-hour exposure.
Sensitization ISO 10993-10	9/12/2002 Covance	Guinea Pig Maximization	Possible mild sensitizer (sensitization rate: 24 hr – 20% 48 hr – 20%

We did not conduct testing for system toxicity, subchronic toxicity, irritation and implantation. The results above in addition to the long and widespread use of these compounds, suggests that there are no biocompatibility issues. A total of 93,000 Cavios units have shipped since 2004; there have been no incidents or adverse reports since 2005. Cavios also carries a CE Mark and was recently re-evaluated in October of 2010.

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ISO 4049:2000 Polymer-based restorative and luting materials:

- Depth of Cure 1.4mm
- Flexural Strength 59.9 Mpa
- Water Sorption 33. $\mu g/mm^3$
- Solubility -0.8 $\mu g/mm^3$

End of 510(k) Summary Section

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NeoDental Chemical Products Co., Ltd.
C/O Mr. Robert Seiple
EMERGO Group, Inc.
611 West 5th Street, Third Floor
Austin, TX 78701

AUG 19 2011

Re: K111668
Trade/Device Name: Cavios® Cavity Liner
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: June 13, 2011
Received: June 14, 2011

Dear Mr. Seiple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 004 - Indication for Use

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111668

Device Name: Cavios® Cavity Liner

Indications for Use:

Cavios® Cavity Liner is to be applied to the interior of a prepared cavity prior to the insertion of restorative materials. Cavios® Cavity Liner is indicated for use in the general dental population.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111668

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